SODIUM BICARBONATE INTRAVENOUS INFUSION

Adopted text for addition to
The International Pharmacopoeia

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Category. Alkalinising agent.

Storage. Sodium bicarbonate intravenous infusion should be kept in a sealed container. Containers that have previously been subjected to heating in an autoclave should not be re-used to keep Sodium bicarbonate intravenous infusion.

Labelling. The designation on the container of Sodium bicarbonate intravenous infusion should state:

- the strength as the percentage m/v of Sodium bicarbonate, as well as the approximate concentrations, in millimoles per litre, of the sodium ions and the bicarbonate ions;
- that containers containing visible particles due to the possible formation of sodium carbonate precipitates must not be used.

Additional information. For a preparation containing 1% m/v of Sodium bicarbonate the concentration of each ion is about 119 millimoles per litre.

Requirements
Complies with the monograph for "Parenteral Preparations".

Definition. Sodium bicarbonate intravenous infusion is a sterile solution of Sodium bicarbonate in Water for injections. It contains not less than 94.0% and not more than 106.0% of the amount of sodium bicarbonate (NaHCO₃) stated on the label.

The infusion is sterilized by a suitable method (see 5.8 Methods of sterilization).
Identity tests

A. The infusion yields reaction A described under 2.1 General identification tests, as characteristic of sodium.

B. Introduce 2 ml of the infusion into a test tube and add 3 ml of acetic acid (~120 g/l) TS. Close the tube immediately using a stopper fitted with a glass tube bent at two right angles. The solution effervesces evolving a colourless and odourless gas. Heat gently and collect the gas in 5 ml of barium hydroxide (15 g/l) TS. A white precipitate is produced which dissolves on addition of an excess of hydrochloric acid (~330 g/l) TS.

Bacterial endotoxins. Carry out the test as described under 3.4 Test for bacterial endotoxins; contains not more than 1.0 IU of endotoxin per ml.

Assay. Titrate a suitable volume of the infusion, accurately measured, containing about 1 g of Sodium bicarbonate with hydrochloric acid (0.5 mol/l) VS using methyl orange ethanol TS as indicator. Each ml of hydrochloric acid (0.5 mol/l) VS is equivalent to 42.00 mg of NaHCO₃.

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